

**DETAILED ACTION**

***Application Status***

1. The Preliminary Amendment filed on 05/25/2006 has been noted and entered.
  
2. Claims 12, 13, 15, 17, 19, 23-32, 36, 38, 40 and 44-46 have been cancelled pursuant to Applicant's Preliminary Amendment filed 05/25/2008, thus claims 1-11, 14, 16, 18, 20-22, 33-35, 37, 39, 41-43, 47 and 48 are pending.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11, 14, 16, 18, 20-22, drawn to an oral solid composition of nateglinide comprising: (a) nateglinide or pharmaceutically acceptable salts thereof; and (b) at least one pharmaceutically acceptable surfactant.

Group II, claim(s) 33-35, 37, 39, 41-43 and 47, drawn to a process for the preparation of a pharmaceutical composition of nateglinide, the process comprising the steps of: (i) blending nateglinide or pharmaceutically acceptable salts thereof, surfactant and one or more pharmaceutically acceptable excipients; and; (ii) processing into a solid dosage form.

Group III, claim(s) 48, drawn to a method for the prevention or treatment of metabolic disorders comprising administering to a patient in need thereof a pharmaceutical composition comprising nateglinide or pharmaceutically acceptable salts thereof; and at least one pharmaceutically acceptable surfactant.

The inventions listed as Groups I, II, and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

An international application should relate to only one invention, or if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any). Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature", should be considered with respect to novelty and inventive step.

The common technical feature in all groups is an oral solid composition of nateglinide comprising: (a) nateglinide or pharmaceutically acceptable salts thereof; and (b) at least one pharmaceutically acceptable surfactant. This composition cannot be a special technical feature under PCT Rule 13.2 because the composition is shown in the prior art.

Ninomiya *et al* (U.S. Publication No. 2004/0014815 A1) disclose a nateglinide-containing preparation wherein the water-soluble polymers or the water-swelling polymers are surfactants, for example, in reference claim 8. Thus, there is no "special technical feature", which renders this restriction requirement proper.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- (a) a cationic surfactant from those disclosed in instant claim 8;
- (b) a filler from those disclosed in instant claim 11; and
- (c) a binder from those disclosed in instant claim 14.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

- (a) a cationic surfactant – Instant claims 1-3, 8-11, 14, 16, 18, 20-22, 33-35, 37, 39, 41-43, 47 and 48;
- (b) a filler – Instant claims 10, 11, 33-35, 37, 39, 41-43 and 47; and
- (c) a binder – Instant claims 10, 14, 33-35, 37, 39, 41-43 and 47.

The following claim(s) are generic: 1-4, 6, 8-11, 14, 16, 18, 20-22, 33, 35, 37, 39, 41-43, 47 and 48.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to the species, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special

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technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 because the instant invention does not set forth a technical relationship among the claimed inventions. For instance, the instant invention lacks unity in that the cationic surfactants set forth in instant claim 8 (e.g. distearyl dimethyl ammonium chloride, decyl amine acetate) do not share a technical relationship, such as a common core structure or biological, physical, or chemical properties. Therefore, with compositions comprising components of varying structural moieties, such as those claimed in instant claim 8, there is not a technical relationship among the claimed inventions.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

#### ***Other Matter***

It is noted by the Examiner that instant claim 44 on page 1 of Applicant's Preliminary Amendment is listed as being cancelled; however, on page 5 of the amended claims, instant claim 44 is missing. The Examiner requests that Applicant revise the claim numbering accordingly, in addition to the requirements set forth above, in reply to this correspondence.

#### ***Conclusion***

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Instant claims 1-11, 14, 16, 18, 20-22, 33-35, 37, 39, 41-43, 47 and 48 are subject to a restriction/election of species requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NELSON C. BLAKELY III whose telephone number is (571) 270-3290. The examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Cecilia Tsang or Janet Andres can be reached on (571) 272-0562 or (571) 272-0867, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. C. B. III/  
Examiner, Art Unit 4131

/Cecilia Tsang/  
Supervisory Patent Examiner, Art Unit 4131